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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,718	03/15/2001	Howard M. Johnson	UF-10164R	5517

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/808,718	JOHNSON ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003 and 06 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,11-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,11-17 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-6, 8, 11-17, and 19-26 are being acted upon.

2. In view of Applicant's amendment and remarks, filed 9/22/03 and 10/06/03, the previous rejections under the second paragraph of 35 U.S.C. 112, and the rejection under 35 U.S.C. 102(b) Kominsky et al., have been withdrawn.

3. Note that "SEB" has been defined, as set forth in the prior art, as *Staphylococcal* enterotoxin B.

4. The declaration filed 10/06/03 has been found to be acceptable.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-13 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:
a method for the treatment of cancer,
does not reasonably provide enablement for:
a method for protecting from cancer, for the reasons of record as set forth in Paper No. 16, mailed 5/16/03.

Applicant's arguments, filed 9/22/03, have been fully considered but they are not persuasive. Applicant argues that the amendment to Claim 1 obviates the rejection and the rejection of all dependent claims.

Applicant has failed to address the rejection as it applies to Claims 12 and 13 as said claims do not depend on Claim 1.

7. As set forth previously, provisional application no. 60/189,346, was filed more than one year prior to the filing of the instant application (3/15/2000), thus, the benefit of priority to said provisional application is denied. Accordingly, the priority date of the instant application is 4/01/2000.

Applicant has indicated agreement with the Examiner's position. Applicant is advised that the first line of the specification must be amended accordingly.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 11, 14-17 , and newly added Claims 20, 21, 23, 24, and 26 stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/26747 (1998, IDS, of record), for the reasons of record as set forth in Paper No. 16, mailed 5/16/03.

Applicant's arguments, filed 9/22/03, have been fully considered but they are not persuasive. Applicant argues that "but for the glib and ambiguous statement at page 19 that the specific antigen and superantigen can be administered separately, there is simply no teaching in the '747 publication of a method where a specific antigen is administered to a patient (prior to and separate from a superantigen), followed by the administration of a superantigen at a later predetermined time and dosage."

It is unclear to the Examiner how Applicant's characterization of the teachings of the prior art as "glib" and "ambiguous" comprises a credible argument in support of Applicant's traversal of the reaction. The reference teaches separate administration of antigen and superantigen in a method that anticipates the method of the instant claims; as such, it teaches the invention of the instant claims.

Applicant argues "In fact, the only discussion regarding an *in vivo* vaccination scheme actually teaches away from the methods as claimed. At page 9 of the '747 publication, end of second paragraph, it states that [I]n vivo anergy is induced by administration of superantigen parenterally or in the form of an adjuvant." This is further echoed at page 79, where the '747 publication teaches that anergy may be produced by preimmunization with peptide in solution followed within 6-30 days by superantigen given parenterally."

Applicant is advised that a complete characterization of the reference would include a discussion indicating that the method of the instant claims can be used to induce an immune response or anergy, depending on the timing of administration of antigen and superantigen. Note that this is a consideration not addressed in the instant specification. This additional teaching in the reference would seem to indicate that the authors of the reference possessed a more complete understanding of the method of the instant claims than did Applicant at the time of filing.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kominsky et al. (2000, IDS, of record), for the reasons of record as set forth in Paper No. 16, mailed 5/16/03.

Applicant's arguments, filed 9/22/03, have been fully considered but they are not persuasive. Applicant argues that "As the reference is not appropriate as a reference under 35 U.S.C. 102(b), it is also not a valid reference under 35 U.S.C. 103."

Applicant is correct in the argument that the reference was not appropriate as a reference under 35 U.S.C. 102(b), however, the reference could have been applied under 35 U.S.C. 102(a). Accordingly, the rejection under 35 U.S.C. 103.(a) is proper.

12. The following are new grounds of rejection necessitated by Applicant's amendment.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-6, 8, 11-17, and 19-26 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) In Claim 1, a method comprising "... a predetermined time interval following said administering of said melanoma specific antigen composition to enhance the cellular immune response to said antigen ...".

B) In Claim 8, a method comprising "... predetermined times and dosages ...".

C) In Claim 12, a method comprising "... tumor specific antigen specific to melanoma.".

D) In Claim 19, the method of claim 14, wherein said activating splenocytes by treating a human or animal in need of such treatment with a tumor antigen vaccination and subsequently administering one or more superantigens is followed by a regimen of booster vaccinations and superantigen administration at predetermined times and dosages, in relation to the timing and dosage of administering said specific antigens.

E) In Claim 20, the method of claim 14, wherein said tumor antigen vaccination comprises at least one antigen associated with melanoma.

F) In Claim 21, the method of claim 14 wherein said subsequently administering on or more superantigens occurs more than seven days after said treating a human or animal in need of such treatment with a tumor antigen vaccination.

G) In Claim 22, the method of claim 15, wherein said method is followed by a regimen of booster vaccinations and superantigen administration at predetermined times and dosages, in relation to the timing and dosage of administering said specific antigens.

H) In Claim 23, the method of claim 15, wherein said antigen vaccination comprises at least one antigen associated with melanoma.

I) In Claim 24, the method of claim 15 wherein said subsequently administering one or more superantigens occurs more than seven days after said treating a human, animal or isolated cell with an antigen vaccination.

J) In Claim 25, the method of claim 16 followed by a regimen of booster vaccinations and superantigen administration at optimized times and dosages, in relation to the timing and dosage of administering said specific antigens.

K) In Claim 26, the method of claim 16 wherein subsequently administering one or more superantigens occurs more than seven days after said treating said human or animal in need of such treatment with a melanoma antigen vaccination.

Applicant indicates that support for the new limitations and new claims can be found throughout the specification.

Regarding the amended claims, no support has been found for the new limitations underlined in A-C above. Regarding the new claims, Applicant has applied specific limitations regarding the enhancement of tumoricidal activity or the enhancing of cytokine production that are not supported by the specification.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

12/29/03
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER